

REMARKS/ARGUMENTS

A Petition for Revival of an Application for Patent Abandoned Unintentionally Under 37 CFR § 1.137(b) is submitted herewith.

After revival of the present application, claims 56-62 will be pending. Claims 1-55 are canceled and claims 56, 57, 59, and 60 are amended in order to comply with the restriction requirement. Applicants reserve the right to prosecute the subject matter of claims 1-55 and claims 56, 57, 59, and 60, as filed, at a later date. After entry of the present amendments, claims 56-62 will be pending and under examination.

Rejection under 35 U.S.C. § 112, first paragraph

The claims are rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of enablement because practice of the claimed inventions allegedly would entail undue experimentation. Applicants respectfully traverse because there is no evidence of record so much as suggesting that those skilled in the art would be unable to practice the claimed inventions. Although the Office Action refers to the reasons set forth in the Office Action dated January 2, 2002 for alleged lack of enablement, a close inspection reveals that these reasons do not support rejection of the present claims.

1. THE STATE OF THE PRIOR ART

The Office Action states that the cytochrome P-450 reductase is not the only enzyme involved in alkaloid metabolism and states that over-expressing the reductase gene does not necessarily ensure that the bottlenecks that have been encountered in attempts to increase alkaloid yields from poppy straw will be overcome, but fails to cite any references (or otherwise identify evidence) supporting the assertion. *In re Wright*, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993) (examiner must provide evidence or technical reasoning substantiating doubts expressed regarding enablement).

2. AMOUNT OF GUIDANCE PRESENTED/
PRESENCE OR ABSENCE OF WORKING EXAMPLES

The Office Action admits that the specification teaches the transformation of poppy plants with recombinant cytochrome P-450 and the subsequent growth of plantlets obtained from the embryos which resulted from transformed plant cells in culture medium, but states that one skilled in the art would not accept on its face the examples provided in the specification as being correlative or representative of the successful generation and harvesting of increased yields of alkaloids from poppy straw. Here, too, the Office Action presents a bare allegation without any supporting evidence.

The Office Action also fails to provide any evidence that the number of working examples provided in the specification would be insufficient for those skilled in the art to practice the claimed inventions. Although the Office Action notes that the specification does not include examples documenting alkaloid contents in transgenic plants, such examples are not required as a condition for patentability. In fact, it is well-established that an applicant need not include *any* working examples demonstrating a claimed invention. *In re Fouche*, 169 U.S.P.Q. 429, 434 (C.C.P.A. 1971). Example 6 provides detailed steps on how to transform poppy plants with cytochrome P-450 reductase genes. Thus, Applicants' provision of representative examples falls far short of demonstrating any lack of enablement.

3. BREADTH OF THE CLAIMS/
QUANTITY OF EXPERIMENTATION

Although the Office Action makes bare assertions that the claims are broad in scope, it fails to provide evidence that their breadth is beyond the level of skill in the art. Notably, the Action fails to provide any evidence that a skilled practitioner would be unable to transform a variety of poppy plant species using conventional methods of plant transformation and regeneration. In fact, those skilled in the art are quite proficient in the art of plant transformation. Given this familiarity, there is no reason to believe that the breadth of the claims would present an impediment to practice of Applicants' claimed inventions.

Although the Office Action asserts that Applicants should have presented comparisons in alkaloid yields between transformed and untransformed plants, the question that remains unanswered is "why?". There is no evidence of record demonstrating that those

skilled in the art would, in fact, have considered such information to have been "necessary" to practice the claimed inventions. Absent some evidence indicating that those skilled in the art having read Applicants' specification would not be able to practice the claimed inventions, there is no reason to believe that the guidance provided in the specification is insufficient within the meaning of §112.

4. THE NATURE OF THE INVENTION

The Office Action fails to provide any evidence that the nature of Applicants' inventions is such that they could not be practiced by those skilled in the art. Thus, as is evident from the foregoing analysis, the Office Action's unsupported contentions as to alleged difficulties that those skilled in the art would encounter in practicing the claimed inventions simply do not constitute evidence or technical reasoning of the sort required to substantiate allegations that there is a lack of enablement.

The Office Action appears to express unwarranted concern that overexpression of cytochrome P-450 reductase, one of several enzymes involved in alkaloid metabolism, does not necessarily result in alterations in the production of the end products of that pathway. In order to demonstrate that overexpression of cytochrome P-450 reductase does, in fact, result in genetically modified poppy plants having straw that has higher or different alkaloid content when compared to straw obtained from non-genetically modified poppy plants, Applicants attach an expert declaration under 37 C.F.R. § 1.132 by Anthony Fist (Exhibit A). As demonstrated by the declaration and accompanying figures, alkaloid content of poppy plants is altered by the introduction of a cytochrome P-450 transgene.

In summary, Applicants submit that the Action has mischaracterized the state of the prior art and the relative skill of those in the art of plant transformation and has improperly rejected the claims as non-enabled. Accordingly, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

The foregoing represents a *bona fide* attempt to advance the present case to allowance. Applicant submits that this application is now in condition for allowance. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully

DOCKET NO.: J&J 1673
Application No.: 09/486,757
Office Action Dated: September 9, 2002

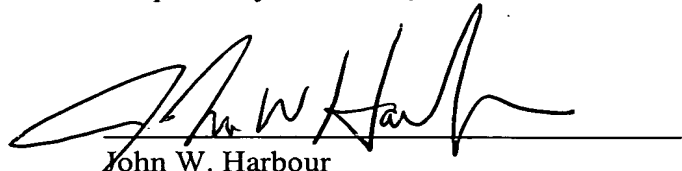
PATENT

requested. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 732-524-2169.

Respectfully submitted,

Date:

12/8/04



John W. Harbour
Registration No. 31,365

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933
Telephone: (732) 524-2169